

**REMARKS**

**I. STATUS OF CLAIMS**

Claims 1-43 are pending in this application. No amendments are made by this reply.

**II. REJECTION UNDER 35 U.S.C. § 103**

**A. Zawistowski**

The Office rejected claims 1-24 and 32-43 under 35 U.S.C. § 103(a) as unpatentable over WO 00/45648 to Zawistowski ("Zawistowski"). Office Action at page 2. In response to Applicants arguments, the Office contends that there is no difference seen between the homogenization of Zawistowski and the homogenization recited in the pending claims. *Id.* Applicants continue to respectfully disagree for the reasons of record and additionally, for the reasons provided below.

As described in Applicants' specification at pages 5 and 6, Zawistowski describes a method for preparing microparticles of plant sterols and stanols by:

- (1) dispensing and suspending the sterols and/or stanols in a semi-fluid, fluid or viscous vehicle; and then,
- (2) exposing the vehicle to impact forces, i.e., high shear forces.

Zawistowski at [0018] - [0021]. These impact forces can be created by using an air-atomization nozzle, a pneumatic nozzle, a *high shear mixer* or colloid mill, or a microfluidizer. *Id.* at [0021]. The Office further directs Applicants to Example 1 in Zawistowski to show that the impact force may be also called homogenization. Office

Action at page 2. As such, the Office asserts that there is no difference between the homogenization of Zawistowski and the homogenization of the claims.

Applicants do not assert a difference in homogenization techniques but instead, submit that different method steps are involved, as is a different order of such step. For example, Zawistowski teaches *suspending* the sterols/stanols and *applying* an impact force. Zawistowski at [0018]-[0021]. This broad teaching is illustrated in Example 1. In Example 1, yoghurt comprising phytosterols/phytostanols is prepared by *suspending* sterols/stanols and powdered milk in a milk mix, *allowing* the milk mix to rehydrate the powdered milk at room temperature for 30 minutes, *homogenizing* the mixture using a microfluidizer, and then *pasteurizing* this mixture to be inoculated with the yoghurt cultures. This example corresponds with the broad teachings of Zawistowski involving suspending and applying an impact force, but the Office attempts to take this teaching a step further. The Office asserts that the 30 minute rehydration of the powdered milk corresponds to Applicants' heating step.

This attempted association between rehydrating and heating, however, is not taught or suggested by Zawistowski. In fact, Zawistowski specifically teaches that "the milk mix was permitted to remain at room temperature for 30 minutes *to rehydrate the milk powder ...*" Zawistowski at [0057] (emphasis added). Instead, it is only by hindsight that the Office extrapolates the tenuous asserted association between rehydration and heating, especially where there is nothing to suggest that the milk was any temperature other than room temperature.

Moreover, Zawistowski's Example 5 is directed to the preparation of a soy drink in which Phytrol, i.e., a phytosterol, is mixed with a soy drink using a batch mixer and

then passed through the microfluidizer and emulsified. *Id.* at [0059], [0060]. Nothing in example 5 suggests a change in temperature to be equated with a heating step.<sup>1</sup> Thus, without a teaching in the specification directed to “heating” the mixture of sterols and aqueous material and prior to being treated with an impact force, the alleged step of “permitt[ing the milk mix] to remain at room temperature for 30 minutes to rehydrate the milk powder” is clearly based on hindsight in a tenuous effort to arrive at the present invention. This is impermissible.

By not teaching all the claim elements, the Office fails to establish a *prima facie* case of obviousness and accordingly, Applicants respectfully request the withdrawal of the rejection.

**B. Yoon**

The Office also rejected claims 1-43 under 35 U.S.C. § 103 as unpatentable over U.S. Patent Application Publication No. 2002/0064548 to Yoon (“Yoon”). Office Action at pages 2, 3. In response to Applicants’ arguments, the Office contends that the claims are open to the inclusion of emulsifiers. *Id.* at page 3. Applicants continue to respectfully disagree for the reasons of record and additionally, for the reasons provided below.

Yoon is directed to “a method of dispensing plant sterols into *micelles* with a size of hundreds of nanometers, which improves the bioavailability of sparingly soluble plant

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<sup>1</sup> The same can be said for Example 2, where no changes in temperature are articulated before the particle size is reduced with an impact force. Zawistowski at [0059], [0060].

sterols, has proper dose proportionality, and shows a maximum of dispersion stability.”

Yoon at [0032] (emphasis added). To produce such micelles, Yoon teaches:

1. admixing plant sterol with an *emulsifier*;
2. melting the admixture by heating at 60 - 200°C;
3. mixing the molten substance with an aqueous beverage; and
4. stirring the mixture at high speed to give a dispersion of plant sterols.

*Id.* at [0033] (emphasis added).

In particular, Yoon specifically teaches that when emulsifying the plant sterol with an emulsifier in *water* (i.e., an aqueous material), “only poor emulsification occurs, resulting in settling the plant sterol into particles with a size ranging from tens to hundreds of micrometers.” Yoon at [0040]. After “intensive research,” Yoon discovered that to produce micelle particles with a size of hundreds of nanometers or less,” one needs to homogenously mix the plant sterol with an emulsifier by heating the plant sterol near its melting point “to bring the two components into liquid phases before mixing.” *Id.* It is only after these steps that the mixture is introduced into “an aqueous beverage or an emulsifier-containing aqueous beverage” that is in contact with a water based liquid. *Id.* at [0041]. Thus, Yoon clearly teaches that water or an aqueous material is not to be heated with the plant sterol and emulsifier. This is further illustrated in Yoon’s examples.

Yoon further states that “[u]pon heating *in the absence of other components*, the plant sterol and an emulsifier come into homogenous contact with each other while being melted, thereby producing micelles with a size of hundreds of nanometers after

the emulsification.” Yoon at [0076] (emphasis added). Yoon’s statement further teaches that the plant sterols and emulsifiers are to be in the absence of other components, i.e., an aqueous material.

The Office’s assertions run contrary to all these teachings in Yoon. For example, to modify Yoon to arrive at the claimed invention, a person of ordinary skill in the art would have to not only mix the plant sterol and emulsifier first *in an aqueous material*, but also heat the plant sterol and emulsifier *in the aqueous material*, which is in direct contrast to Yoon’s express teachings. As provided in the present specification, “*the aqueous material* can comprise *water*, and *water* with additional compounds, and compositions dissolved or dispersed in it, either as dispersion of solids in *water* or an emulsion of a liquid in *water* or *water* in a liquid.” Applicants’ specification at page 14, [044] (emphasis added).

Even though “the claims are open to the inclusion of emulsifiers” (Office Action at pages 2, 3), Yoon would have to teach away from such modifications to arrive at the present invention under the Office’s rationale. In fact, one would be changing Yoon’s principle of operation. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” M.P.E.P. § 2143.02(VI) (citing *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959)). As such, the Office fails to establish a *prima facie* case of obviousness without providing a suggestion or motivation to modify the teachings of Yoon.

Accordingly, Applicants respectfully request the withdrawal of the rejection.

### III. CONCLUSION


In view of the foregoing remarks, Applicants submit that the cited art, taken alone or in combination, does not render obvious the presently claimed invention. Applicants therefore request the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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